IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN THE APPLICATION OF:

GARY M. FADER

CASE NO.: BB1071USDIV2 APPLICATION NO.: 10/757667

CONFIRMATION NO.: 7292 GROUP ART UNIT: 1638

EXAMINER: VINOD KUMAR FILED: JANUARY 14, 2004

FOR: SUPPRESSSION OF SPECIFIC CLASSES OF SOYBEAN SEED PROTEIN GENES

Via EFS-Web

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Reply to Examiner's Answer to Appeal Brief

This is in response to the Examiner's answer to the Appeal Brief filed 03/17/2009 and 04/29/2009 from the Office Action mailed 10/15/2008.

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(I) Real Party in Interest

The real party in interest in this Appeal is E. I. du Pont de Nemours and Company, the assignee of the entire right, title and interest of the above-identified patent application.

(II) Related Appeals and Interferences

There are no related Appeals or Interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal.

(III) Status of Claims

Claims 1-21 were originally filed.

Claims 22-24 were entered by Preliminary Amendment, claims 2-21 were cancelled and claim 1 was retained for purposes of continuity and it was cancelled upon entry of the Preliminary Amendment.

There are three independent claims: 22, 23 and 24.

The currently pending and appealed claims are claims 22, 23 and 24 which are set forth in the Claims Appendix attached hereto.

(IV) Status of Amendments Filed Subsequent to Final Rejection

A Response after Final was filed electronically on December 18, 2008 and was entered for purpose of this Appeal according to the Advisory Action electronically delivered on February 9, 2009.

(V) Summary of the Invention

The invention on appeal concerns food comprising a soy protein product prepared from transgenic soybeans seeds having a reduced quantity of soybean seed storage protein prepared by methods recited in the claims and, also, that constitute the subject matter of U.S. Patent No. 6,703,544 issued on March 9, 2004 to Fader et al.

Claim 22 recites food comprising a soy protein product prepared from transgenic soybean seeds having a reduced quantity of soybean seed storage protein and prepared by a method comprising:

(a) constructing a chimeric gene comprising:

(i) a nucleic acid fragment comprising a promoter that is functional in the cells of soybean seeds;

(ii) a nucleic acid fragment encoding all or a portion of a soybean seed storage protein placed in sense or antisense orientation relative to the promoter of (i) wherein said soybean seed storage protein is selected from the group consisting of glycinin and β-conglycinin; and

(iii) a transcriptional termination region;

(b) creating a transgenic soybean cell by introducing into a soybean cell the chimeric gene of (a); and

(c) growing the transgenic soybean cells of step (b) which express the chimeric gene of step (a)

wherein the quantity of one or more members of a class of soybean seed storage protein subunits is reduced when compared to soybean seeds not comprising the chimeric gene of step (a), and wherein the class of soybean seed storage protein subunits is selected from the group consisting of: glycinin and β-conglycinin.

Support for this claim can be found on pages 1 and 2 and elsewhere in the specification, in particular, the examples and claims as originally filed.

Claim 23 is similar to Claim 22 except that food comprises a soy protein product prepared from transgenic soybean seeds prepared by a method for simultaneously reducing expression of two soybean genes. Support for this claim can be found on pages 1-2 of the specification, and elsewhere in the specification, in particular, the examples and claims as originally filed.

Claim 24 recites food comprising a soy protein prepared from transgenic soybean seeds obtained from a soybean plant transformed at a single locus in its

genome with a chimeric gene comprising at least a portion of a glycinin or a β-conglycinin gene for reducing the amount of at least one soybean seed storage protein in soybean seeds wherein the seed storage protein is selected from the group consisting of glycinin and β-conglycinin, when compared to seeds obtained from a soybean plant not comprising the chimeric gene in its genome.

Support for this claim can be found on pages 1-2 of the specification, in Example 2 and further data relating to Example 2 was set forth in the declaration of Dr. Anthony Kinney, one of the co-inventors of the subject application. A copy of Dr. Kinney's declaration dated June 29, 2001 was set forth previously in Evidence Appendix A. Also included previously in Evidence Appendix B, was a copy of Dr. Gary Fader's declaration dated June 27, 2001. Dr. Fader's declaration shows that all the glycinin subunits were suppressed when truncated form of the G1 and G4 subunits were expressed in a sense orientation under the control of a Kti promoter.

(VI) Grounds of Rejection To Be Reviewed on Appeal

There are two grounds of rejection presented for review:

a) Whether claims 22, 23 and 24 are anticipated under 35 USC §102(b) or, in the alternative, are rendered obvious under 35 USC §103(a) over Trueblood et al. (U.S. Patent No. 4,267,118 issued on May 12, 1981?

b) Whether claims 22, 23 and 24 are anticipated under 35 USC §102(b) or, in the alternative, are rendered obvious under 35 USC §103(a) over Staswick et al. (Archives of Biochemistry and Biophysics, 223:1-8 1983)?

(VII) Argument

(a) The rejection of claims 22, 23 and 24 as anticipated under 35 USC §102(b) or, in the alternative, as rendered obvious under 35 USC §103(a) over Trueblood et al. (U.S. Patent No. 4,267,118 issued on May 12, 1981.

Claims 22-23 concern food comprising a soy protein prepared from transgenic soybean seeds prepared according to the methods recited therein.

The examiner maintains that the claimed food has the same structural limitations as taught by Trueblood et al. The '118 patent (Trueblood et al.) concerns a process for treating crude soybean oil to make it a food or commercial grade quality. It is stated in column 4 at lines 41 to 48 that

> the **protein level** in the supernatant oil or that being separate from the treatment vessels as above described, was found to be **less than 0.1 gram protein per 100 grams of oil (0.1%)**. A protein analysis of the crude soybean oil prior to treatment in accordance with the present invention showed a level of 1.5 gram protein per 100 grams of oil (1.5%). (Emphasis added.)

Thus, the method of Trueblood et al. is to produce a food grade quality soybean oil from crude soybean oil wherein the resulting food grade quality soybean oil has a protein content of less than 0.1%.

Submitted previously in Evidence Appendix C was a copy of a portion of Soy Protein Products: Characteristics, Nutritional Aspects and Utilization published by the Soy Protein Council (1987). It is stated on page 1 of this reference that

> Soy protein products fall into three major groups. These groups are based on protein content, and range from 40% to over 90%. All three basic soy protein product groups (except full-fat flours) are derived from defatted flakes. They are: soy flours and grits, soy protein concentrates and soy protein isolates (Table 1). . . .

It is clear that, by definition, the lowest level of soy protein in a soy protein product is about 40% protein. Clearly, a food grade soybean oil having less than 0.1% protein does not constitute a soy protein product by even the wildest stretch of the imagination and constitutes merely an impurity.

Also, submitted previously in Evidence Appendix D was a printout from the soy foods web page, www.soyfoods.org. This also shows that a soy protein product such as soy flour would have at least 40% protein.

Accordingly, one of ordinary skill in the art is inexorably led to the conclusion that a soy protein product would have at least about 40% protein and that a **food-grade quality oil having less than 0.1% protein does not constitute a soy protein product** as that term is defined as set forth in the aforementioned publication by the Soy Protein Counsel.

The contention that the food of the instant invention comprising a soybean protein product prepared from transgenic soybeans seeds having a reduced quantity of soybean seed storage protein prepared by methods recited in the claims is anticipated by a food grade soybean oil having less than 0.1% protein as described by Trueblood et al. is utterly without merit.

Those skilled in the art know that a soybean protein product, by definition, has a protein content of at least 40% as supported by the discussion of the references in Evidence Appendices C and D. A food grade soybean oil having less that 0.1% protein does not, even remotely, come close to minimum level of about 40% protein that characterizes a soybean protein product.

Further it is again reiterated that the intent of the instant invention is to create transgenic soybeans comprising reduced quantity of soybean seed storage proteins for the production of soy protein products to be incorporated in food. This is supported throughout the specification and for example on page 1, lines 5-9, where it is stated that:

"This invention concerns the construction of transgenic soybean lines wherein the expression of genes encoding seed storage proteins is modified to effect a change in seed storage protein profile of transgenic plants. Such modified transgenic soybean lines are used for the production of ***novel soy protein products with unique and valuable functional characteristics*** (emphasis added)*."*

Thus, in view of the specification, the arguments presented above, and the knowledge available to one with experience in the field of the invention it becomes evident that the argument that a food comprising a soy protein product reads on a food grade oil with remnant amounts of oil body proteins at less than 0.1% protein, clearly conflicts with the art-accepted meaning of the term "soy

protein products" and foods comprising them and the intent of the instant invention.

b) The rejection of claims 22, 23 and 24 as anticipated under 35 USC §102(b) or, in the alternative, are rendered obvious under 35 USC §103(a) over Staswick et al. (Archives of Biochemistry and Biophysics, 223:1-8 1983).

Staswick et al. are concerned with improving the nutritional quality of soybean seed protein by altering glycinin subunit composition. The cultivar used in the in study does not appear to be transgenic. The focus of Staswick et al. is in improving the nutritional quality of glycinin storage protein by replacing subunits having a low methionine content with those having a higher methionine content.

In contrast, the instant invention concerns food comprising a soy protein product prepared from transgenic soybean seeds having a reduced quantity of soybean seed storage protein .....wherein the quantity of one or more members of a class of soybean seed storage protein subunits is reduced when compared to soybean seeds not comprising the **chimeric *gene*** (emphasis added) of step (a), and wherein the class of soybean seed storage protein subunits is selected from the group consisting of glycinin and β-conglycinin.

"***Chimeric gene***" (emphasis added) is defined in the specification on page 8, lines 17-28 *"as a gene that comprises heterogeneous regulatory and coding sequences not found in nature*."

It is stated on page 6 of the Office Action dated October 15, 2008 and on page 12 of the 'Examiner's Answer' dated July 9, 2009, that
". . .it is noted that the features upon which applicant relies (i.e., soy protein products as claimed contains chimeric construct) are not recited in the rejected claim(s). . . ."

Such features are, at a minimum, **inherently** present in the claimed invention .

Food of the instant invention comprises a soy protein product prepared from transgenic soybean seeds having a reduced quantity of soybean seed storage protein .....wherein the quantity of one or more members of a class of soybean seed storage protein subunits is reduced when **compared to soybean seeds not comprising the chimeric gene** (emphasis added) of step (a), and wherein the class of soybean seed storage protein subunits is selected from the group consisting of: glycinin and β-conglycinin.

Thus, food comprising a soy protein product prepared by the method of the instant invention and as recited in the claims would be expected to contain detectable levels of all or part of the recombinant DNA construct, used to create transgenic soybeans. This is, for example, discussed further in several scientific publications and for example in "The effect of processing parameters on DNA degradation in food"; Baueret al., European Food Research and Technology (2003), 217(4), 338-343)." , wherein it is stated that:

*"**Soymilk and tofu were produced from genetically modified soybeans**.* (emphasis added) *After boiling (10 min) of raw soymilk, the detectable fragment length decreased from 1,714 to 1,339 bp. The study of the final tofu product did not reveal any further DNA degradation.* ***In common soy protein isolate, a rather highly processed food, DNA fragments of at least 714 bp were detected"*****(**emphasis added**).**

Accordingly, food of the instant invention comprising a soy protein product as recited in the claims would be distinguishable by the presence of the chimeric gene used to create the transgenic soybean plant producing the seeds from which the soy protein products were obtained.

Methods for detection of chimeric genes in biological and in food material a very well known in the art and performed on a routine basis by those skilled in the art.

(VIII) Conclusion

In view of the foregoing discussion, Applicants maintain that: :

a) claims 22-24 are neither anticipated under 35 USC §102(b) nor rendered obvious under 35 USC §103(a) over Trueblood et al.; and

b) claims 22-24 under 35 USC §102(b) are not anticipated by, or in the alternative, under 35 USC §103(a) obvious over Staswick et al

Accordingly, the Board is respectfully requested to reverse the final rejection of pending claims 22, 23, and 24 and indicate allowability of all claims.

Enclosed herewith is a Petition for a one (1) month extension of time to permit the filing of the Brief on Appeal. Please charge the fee for extension of time of one (1) month, as well as the requisite fee set forth in 37 CFR §1.17(f), to Appellant's Assignee's (E. I. du Pont de Nemours and Company) Deposit Account No. 04-1928.

Respectfully submitted,

/Lila A. T. Akrad/

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Claims Appendix

Claim 22. (previously presented) Food comprising a soy protein product prepared from transgenic soybean seeds having a reduced quantity of soybean seed storage protein and prepared by a method comprising:

(a) constructing a chimeric gene comprising:

(i) a nucleic acid fragment comprising a promoter that is functional in the cells of soybean seeds;

(ii) a nucleic acid fragment encoding all or a portion of a soybean seed storage protein placed in sense or antisense orientation relative to the promoter of (i) wherein said soybean seed storage protein is selected from the group consisting of glycinin and β-conglycinin; and

(iii) a transcriptional termination region;

(b) creating a transgenic soybean cell by introducing into a soybean cell the chimeric gene of (a); and

(c) growing the transgenic soybean cells of step (b) which express the chimeric gene of step (a)

wherein the quantity of one or more members of a class of soybean seed storage protein subunits is reduced when compared to soybean seeds not comprising the chimeric gene of step (a), and wherein the class of soybean seed storage protein subunits is selected from the group consisting of: glycinin and β-conglycinin.

Claim 23. (previously presented) Food comprising a soy protein prepared from transgenic soybean seeds prepared by a method for simultaneously reducing the expression of two soybean genes comprising:

(a) constructing a chimeric gene comprising:

(i) a nucleic acid fragment comprising a promoter region from a soybean seed storage protein gene; and

(ii) a nucleic acid fragment encoding all or a portion of a soybean protein that is not the soybean seed storage protein of (i) wherein said soybean seed storage protein is selected from the group consisting of glycinin and β-conglycinin, said nucleic acid fragment placed in a sense or antisense orientation relative to the promoter of (i), and (iii) a transcriptional termination region;

(b) creating a transgenic soybean seed by introducing into a soybean seed the chimeric gene of (a); and

(c) growing the transgenic soybean seeds of step (b) which express the chimeric gene of step (a);

wherein the quantity of one or more members of a class of soybean seed storage protein subunits and the quantity of the protein encoded by the nucleic acid fragment of (a)(ii) is reduced when compared to soybeans seeds not comprising the chimeric gene of step (a), and wherein the class of soybean seed storage protein subunits is selected from the group consisting of glycinin and β-conglycinin.

Claim 24. (previously presented) Food comprising a soy protein prepared from transgenic soybean seeds obtained from a soybean plant transformed at a single locus in its genome with a chimeric gene comprising at least a portion of a glycinin or a β-conglycin gene for reducing the amount of at least one soybean seed storage protein in soybean seeds wherein the seed storage protein is selected from the group consisting of glycinin and β-conglycinin, when compared to seeds obtained from a soybean plant not comprising the chimeric gene in its genome.

Related Proceedings Appendix

None